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Amendments to China's GMO Safety Assessment Regulations

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Report Highlights:
On April 27, 2015, the Chinese Ministry of Agriculture (MOA) announced the "Proposed Amendments to the Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (GMOs)" for public comments. China also notified these proposed amendments to the WTO as SPS 881 on June 2, 2015. The WTO comment period end on August 1, 2015. Interested stakeholders can submit their comments directly via email to: sps@aqsiq.gov.cn.
This report provides the unofficial translation of the proposed amendments and a comparison of the current regulations and the amendments.

Executive Summary:

On April 27, 2015, the Chinese Ministry of Agriculture (MOA) announced the "Proposed Amendments to the Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (GMOs)" for public comments. China also notified these proposed amendments to the WTO as SPS 881 on June 2, 2015. The WTO comment period ends on August 1, 2015. Interested stakeholders can submit their comments directly via email to: sps@aqsiq.gov.cn. Courtesy copies can be sent to AgBeijing@fas.usda.gov and to Roseanne.Freese@fas.usda.gov. This report provides the unofficial translation of the proposed amendments and a comparison of the current regulations and the amendments.

BEGIN TRANSLATION

Amendment on the *Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms*

Ministry of Agriculture (MOA) of China decided to make following amendment to the ***Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms:***

1. Amend Article 5 Item 1 as:

According to Article 9 of the Regulations, a national biosafety committee (NBC) shall be established and in charge of safety assessment of agricultural GMOs. The NBC shall be composed of experts who are engaged in biological research, production, processing, inspection and quarantine with respect to agricultural GMOs, as well as experts in the fields of public health and environmental protection. The office term of the NBC shall be five years.

2. Amend Article 6 as:

Organization engaged in research and testing of agricultural GMOs is the first responsible person for Agricultural GMO safety management, who shall set up an institutional biosafety committee of agricultural GMOs (IBC), which shall be headed by the legal representative of the organization. The IBC shall be in charge of the supervision over the safety of agricultural GMOs and the examination of applications for safety assessment of agricultural GMOs in the organization.

Organizations engaged in research and testing of agricultural GMOs shall formulate operating procedures for agricultural GMO tests, and strengthen the traceability management of agricultural GMO tests.

3. Amend Article 16 as:

The accepted applications shall be handed over to National Biosafety Committee (NBC) for safety assessment. After the Ministry of Agriculture receives the safety assessment result, a decision on the application shall be made according to the Administrative License Law of People's Republic of China and the Regulations on Administration of Agricultural Genetically Modified Organisms Safety (promulgated by State Council Decree No. 304 in 2001), with scientific, economic and social factors being comprehensively taken into consideration.

4. Amend Article 22 Item 2 as:

When submitting an application mentioned in the preceding paragraph, the organization engaged in the testing shall provide the following materials according to requirements of relevant safety assessment guidelines:

For applications for productive tests, samples materials, control materials and detection method of the agricultural GMOs shall be submitted as required.

5. Add a new Article after Article 22

Within the validity period of the Agricultural GMO Safety Permits, when there is a need to change the test location, the organizations engaged in the testing shall report to the Agricultural GMO Safety Administration Office.

6. Amend Article 23 Item 1 and Item 2 as:

Item 1:
When an agricultural GMO is intended to apply for a safety certificate after finishing testing, the organization engaged in the testing shall apply to the Agricultural GMO Safety Administration Office. Only after passing the safety assessment of the NBC and obtaining the approval of the Ministry of Agriculture, can the safety certificate of agricultural GMOs be issued.

Item 2:
When submitting an application mentioned in the preceding paragraph, the organization engaged in the testing shall provide the following materials according to requirements of relevant safety assessment guidelines:

1) An application for safety assessment (see Appendix V);
2) The safety class of agricultural GMOs and justification for the class determination;
3) Inspection report(s) from technical inspection body entrusted by the MOA;
4) Summary report(s) on the tests in the stages of restricted field-testing, enlarged field-testing, and productive testing.
5) Sample materials, control materials and detection methods of the agricultural GMOs as required; with the exception of those already been submitted in accordance to the Article 22.

7. Amend Article 25 as:

When introducing agricultural GMOs from outside the People's Republic of China or exporting agricultural GMOs to the People's Republic of China, the introducing entity or exporter shall provide relevant safety assessment materials in accordance with "Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms", sample materials, control materials and detection methods of the agricultural GMOs shall be provided as well when applying for safety certificates.

8. Amend Article 26 as:

When submitting an application for safety assessment of agricultural GMOs, the applicant shall pay assessment fees and inspection fees in accordance with the relevant regulations of the Ministry of Finance and the National Development and Reform Commission (NDRC).

9. Article 34

Organizations engaged in the testing and/or production of the agricultural GMOs shall be subject to the supervision and inspection of the agricultural administrative departments, and an annual testing and production summary report of the previous year shall be submitted before March 31 to the agricultural administrative departments at the provincial- and county government level where the testing and/or the production of agricultural GMOs is conducted.

Additionally, necessary amending were made to relevant items of the Annex.

The amendment will take effect on xx/xx/2015.

The *Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms* will be revised based on this amendment and re-promulgated.

XX/XX/2015

Appendix 3

Article Comparison Table of the Appendix of *Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms (GMOs)* before and after Revision

Before revision	After revision
Appendix I: III. Application requirements for safety assessment of GM plants at each stage	**Appendix I: III. Application requirements for GM plants at each stage**
1.2. Number of GM plants for experiment in one application: **no more than 20 transformants**. The transformants should be obtained from the same species of recipient plant (not exceeding five varieties or strains), the same gene and the same genetic manipulation practice. And each transformant should be clearly named or coded.	1.2 Number of GM plants for experiment in one application: the transformants should be obtained from the same species of recipient plant (not exceeding five varieties or strains), the same gene and the same genetic manipulation practice. And each transformant should be clearly named or coded.
1.3. Experiment site location and scale: **no more than2 provinces and 3 sites per province with the total acreage** not exceeding 4 mus/about 0.27 ha (perennial plants should depend on specific situations). The location description should be in detail and include province (municipality, autonomous region), county (city), town and village.	1.3. Experiment site location and scale: **experiments should be conducted in the experiment base of the legal entity with the acreage of every experiment site** not exceeding 4 mus/about 0.27 ha (perennial plants should depend on specific situations). The location description should be in detail and include province (municipality, autonomous region), county (city), town, village and **coordinates**.
	1.5.6 Operational procedure for the pilot experiment (including measures taken for the storage, transfer, disposal, harvest, post-harvest monitoring, andaccidental release of GM plants and the management of testing sites etc.)
2.2 Number of GM plants for experiment in one application: **not exceeding 5 transformants.** The transformants should be obtained from the same strain or line of recipient plants, the same target gene and the same genetic manipulation practice. And each transformant should have a clear name or code consistent with that used in the pilot experiment stage.	2.2 Number of experimented GM plants in one application: the transformants should be obtained from the same strain or line of recipient plants, the same target gene and the same genetic manipulation practice. And each transformant should have a clear name or code consistent with that used in the pilot experiment stage.

2.3 Experiment site location and scale: **no more than 2 provinces and 7 sites per province with the total acreage being between 4 to 30 mus/0.27 to 2 ha**(perennial plants depend on specific situations). The location description should be indetail and include province (municipality, autonomous region), county (city), town and village.	2.3 Experiment site location and scale: **the acreage of each experiment site should not exceed 30 mus** (**generally exceeding 4 mus/0.27ha** (perennial plants depend on specific situations). The location description should be in detail and include province (municipality, autonomous region), county (city), town, village and **coordinates**.
	2.5.7 Operational procedure for environmental release (including measures taken for the storage, transfer, disposal, harvest, post-harvest monitoring and accidental release of GM plants and the management of the testing sites etc.)
3.2 Number of GM plants for experiment in one application: **one line** for one application. The name of the line should be consistent with the name or code used in previous tests.	3.2 Number of GM plants for experiment in one application: **not exceeding 5 lines that belong to the same transformant.** The names of the lines should be consistent with those in the previous experiment stage.
3.3 Experiment site location and scale: **no more than 2 provinces and 5 sites per province with the total acreage** being more than 30 mus/2 ha (perennial plants depend on specific situations). The location description should be in detail and include province (municipality, autonomous region), county (city), town and village.	3.3 Experiment site location and scale: provinces (municipalities, autonomous regions) where environmental release is approved of should be selected with **the acreage of each experiment site** exceeding 30 mus/2 ha (perennial plants depend on specific situations). The location description should be in detail and include province (municipality, autonomous region), county (city), town, village and **coordinates**.
	3.5.8 Operational procedure for the productive field trial(including measures taken for the storage, transfer, disposal, harvest, post-harvest monitoring and accidental release of GM plants and the management of the testing sites etc.)

4.1 The title of the project: should include 1) the name of foreign gene(s); 2) the name of recipient plant; 3) the location **(province/municipality/autonomous region))**, for example. "the safety certificate for the application of Bt cotton XY12 transformed with the cry1Ac gene in Shandong Province".	4.1 The title of the project: should include 1) the name of foreign gene(s); 2) the name of recipient plant; 3) the **applicable ecological zone** of the safety certificate, for example, "the safety certificate for the application of Bt cotton XY12 transformed with the cry1Ac gene in the **Yellow River Basin**".
4.2 Number of GM lines (or varieties) in one application: one line (or variety). Its name should be consistent with the name or code in the previous experiment stage.	4.2 Number of GM lines (or varieties) in one application: one line (or variety). Its name should be consistent with the name or code in the previous experiment stage and follow the *Regulations for the Naming of Agricultural Plant Varieties*.
4.3 The safety certificate should be applied for one line (or variety) of a GM plant in one **provincial administrative region** where the productive field trial has been approved and done.	4.3 The safety certificate should be applied for one line (or variety) of a GM plant in one **applicable ecological zone** where the productive field trial has been approved of and done.
Appendix II: III.Data requirements for the application of GM animals in each stage.	**Appendix II: III. Data requirements for the application of GM animals in each stage.**
1.2 Number of GM animals for experiment: The number of **lines (materials) of GM animals should not exceed 5** in an application. These lines should be acquired from the same recipient animal and the same target gene through the same genetic manipulation practice. Moreover, each line (material) should have a definite designation or code.	1.2 Number of GM animals for experiment: GM animal lines (materials) in an application should be acquired from the same recipient animal and the same target gene through the same genetic manipulation practice. Moreover, each line (material) should have a definite designation or code.
1.3 Experiment site location and scale: **not more than 2 provinces, and not more than 3 sites in each province. Total scale (maximum)**: 10-20 heads for big animals (horses, cattle), 20-40 for medium or small animals (pigs, sheep), 100-200 for poultry (chickens, ducks etc.), 2000-5000 for fish, etc. The province (municipality or autonomous region), county(city), town and village of the experiment site should be specified clearly.	1.3 Experiment site and scale: **experiments should be conducted in the experiment base of the legal entity. The scale of each experiment site (maximum)**: 10-20 heads for big animals (horses, cattle), 20-40 for medium-sized or small animals (pigs, sheep), 100-200 for poultry (chickens, ducks etc.), 2000-5000 for fish, etc. The province (municipality or autonomous region), county (city), town, village and **coordinates** of the experiment site should be specified clearly.
	1.5.6 The operational procedure for pilot experiments (including measures taken for the storage, feeding,

	slaughter, disposal and post-experiment monitoring of GM animals ,handling of accidents-and the management of the experiment sites.
2.2 Number of GM animals for experiment: GM animals in an application **should not exceed three lines**. And these lines should be acquired from the same species of recipient animals, the same target gene and the same genetic manipulation practice. And each line should have a designation or code consistent with that in the pilotexperiment stage.	2.2 Number of GM animals for experiment: GM animals in an application **should not exceed five lines**. And these lines should be acquired from the same species of recipient animals, the same target gene and the same genetic manipulation practice. And each line should have a designation or code consistent with that in the pilot experiment stage.
2.3 Experiment site location and scale: **nomore than 2 provinces and no more than 3 sites in each province. Total scale (maximum)** is 150 for big animals (horses and cattle), 500 for medium-sized and small animals (pigs, sheep etc.), 3000 for poultry (chickens ,ducks etc.) and 10000 to 50000 for fish etc. The specific province (municipality, autonomic region), county (city), town and village of the experiment site should be pointed out clearly.	2.3 Experiment site and scale: **the scale of each experiment site (maximum)** is 150 for big animals (horses and cattle), 500 for medium-sized and small animals (pigs, sheep etc.), 3000 for poultry (chickens, ducks etc.) and 10000 to 50000 for fish etc. The specific province (municipality, autonomic region), county (city), town, village and **coordinates** of the experiment site should be pointed out clearly.
	2.5.7 The operational procedure for environmental release (including measures taken for the storage, feeding, slaughter, disposal and post-experiment monitoring of GM animals, the handling of accidents and the management of the experiment sites etc..
3.2 Number of GM animals in experiment: **there should be only one line or variety of GM animals** in an application. And the line should have a clear designation in accordance with the designation or code in the previous testing stage.	3.2 Number of GM animals in experiment: there **should not be more than three lines of GM animals in an application. These lines should be acquired from the same species of recipient animals, the same target genes and the same genetic manipulation practice.** And the lines or varieties should have a clear designation in accordance with the designation or code in the previous testing stage.
3.3 Experiment site location and scale: the experiment should be carried out in the province (municipality, autonomous region) authorized with environmental release. **No more than two provinces should be chosen and no more than two sites should be chosen in each province. Total**	3.3 Experiment site and scale: the experiment should be carried out in the province (municipality, autonomous region) authorized with environmental release. **The scale of each experiment site (maximum)** is 1000 for big animals (horses

scale (maximum) is 1000 for big animals (horses and cattle), 10000 for medium and small animals (pigs, sheep etc.), 20000 for poultry (chickens, ducksetc.) or 100 thousand to 300 thousand for fish etc. The province (municipality, autonomic region), county (city), town and village of the experiment site should be specified clearly.	and cattle), 10000 for medium and small animals (pigs, sheepetc.), 20000 for poultry (chickens, ducks etc.) or 100 thousand to 300 thousand for fish etc. The province (municipality, autonomous region), county (city), town, village and **coordinates** of the experiment site should be specified clearly.
	2.5.7 The operational procedure for the productive field trial(including measures taken for the storage, feeding, slaughter, disposal and post-experiment monitoring of GM animals, the handling of accidents and the management of the experiment sites etc..
4.1 Project title: it should include **the designation** of the target gene, of the GM animals and **of the applied province (municipality or autonomous region)**, for example, safety certificate of growth-promoting GH gene transferred A112 carp **in Hunan province**.	4.1 Project title: it should include the designation of the target gene and of the GM animals, for example, safety certificate of growth-promoting GH gene transferred A112 carp.
4.3 One safety certificate should be applied for one species of GM animals in the administrative region of the province where the productive field trial has beenauthorized.	**deleted**
Appendix III:I. Safety assessment of GM microorganisms for plant use III. Data requirements for the application for GM microorganisms for plant use at each stage	**Appendix III: I. Safety assessment of GM microorganisms for plant use III. Data requirements for the application for GM microorganisms for plant use at each stage**
1.2 Number of strains of GM microorganisms used in experiments: **no more than twenty strains** for one application. These strains shall be obtained using the same species of recipient microorganisms (no more than five strains of recipients), the same target gene and the same genetic manipulation practice and each of them shall be named or coded clearly.	1.2 Number of strains of GM microorganisms used in experiments: strains in an application shall be obtained using the same species of recipient organisms (no more than five strains of recipients), the same target gene and the same genetic manipulation practice and each of them shall be named or coded clearly.
1.3 Experiment site location and scale: no more than two provinces and no more than 3 sites for each province with the total experimental area being no more than 4 mus (about 0.27 ha). The province (municipality or autonomous region), county (city), town and village of the location of eachexperimental site should be clearly identified.	1.3 Experiment site location and scale: experiments **should be conducted in the experiment base of the legal entity** with **the acreage of each experiment site** not exceeding 4 mus (about 0.27 ha). The province (municipality, autonomous region), county (city), town, village and **coordinates** of the

	location of each experiment site should be clearly identified.
	1.5.5 The operational procedure for the pilot experiment(including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM animals, the handling of accidental release and the management of the experiment sites etc..
2.2 Number of strains of GM microorganisms used in experiments: **no more than5 strains** for one application. These strains should be obtained using the same species of recipient microorganism, the same target gene and the same genetic manipulation practice. Definitive names of strains are required and should be consistent with the names used in the pilot experiment stage.	2.2 Number of strains of GM microorganisms used in experiments: strains of an application should be obtained using the same species of recipient microorganisms, the same target gene and the same genetic manipulation practice. Definitive names of strains are required and should be consistent with the names used in the pilot experiment stage.
2.3 Experiment site location and scale: **no more than two provinces and no more than 5 sites for each province with the total experiment area being 4-30 mus(0.27ha-2ha).** The province(municipality, autonomous region),county (city), town and village of the location of each experiment site should be clearly identified.	2.3 Experiment site location and scale: the area of each experiment site should not exceed 30 mus/2ha (generally above 4 mus/0.27 ha). The province (municipality, autonomous region), county (city), town, village and coordinates of the location of each experiment site should be clearly identified.
	2.5.7 The operational procedure for environmental release (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM animals, the handling of accidental release and the management of the experiment sites etc..
3.2 Number of strains of GM microorganisms for experiment: **only one strain of GM microorganisms** in one application. And a definitive name of each strain is required to match that used in previous experiment stages.	3.2 Number of strains of GM microorganisms for experiment: **not exceeding five strains (lines) of GM microorganisms in an application. The strains (lines) should be obtained from the same recipient strain, the same target gene and the same genetic manipulation practice .**And a definitive name of each strain is required to match that used in previous experiment stages.
3.3 Experiment site location and scale: experiments should be conducted in	3.3 Experiment site location and scale: experiments should be

provinces (municipalities, autonomous regions) which are approved of for environmental release. **No more than two provinces and no more than 3 sites for each province should be selected with the total area of the experiment sites exceeding 30 mus (2 ha).** The specific province (municipality, autonomous region), county (city), town and village of each experiment site should be identified clearly.	conducted in provinces (municipalities, autonomous regions) which are approved of for environmental release. **The area of each experiment site should exceed 30 mus (2 ha)**. The specific province (municipality, autonomous region), county (city), town, village and **coordinates** of each experiment site should be identified clearly.
	3.5.8 The operational procedure for the productive field trial (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM animals, the handling of accidental release and the management of the experiment sites etc..
4.1 Title of project: it should include the name of the target gene, of the GM microorganism and of **the province (municipality, autonomous region) where the safety certificate will be applied**, for example, safety certificate for CrylAc gene transferred Bt NY23 **in Guangdong**.	4.1 Title of project: it should include the name of the target gene and of the GM microorganism, for example, safety certificate for CrylAc gene transferred Bt NY23.
4.2 With the completion of the productive field trial, safety certificates can be appliedfor GM microorganisms. One safety certificate can be applied for only one strain (line) of GM microorganism in only one provincial level administrative region where the productive field trial has been approved.	**4,2 A safety certificate for a GM microorganism can only be applied with the completion of the productive field trial which has been approved by the Ministry of Agriculture.**
Appendix III：II. The safety assessment of GM microorganisms for animal use III. Data requirement of application for different stages of GM microorganisms for animal use	**Appendix III：II. The safety assessment of GM microorganisms for animal use III. Data requirement of application for different stages of GM microorganisms for animal use**
1.2 Number of strains of GM microorganisms used in experiments: **no more than twenty strains** for one application. These strains shall be obtained using the same recipient (no more than five strains of recipients), the same Target gene and the same genetic manipulation practice. And each GM strain should be clearly named or coded.	1.2 Number of strains of GM microorganisms used in experiments: strains in one application should be obtained using the same recipient (no more than five strains of recipients), the same target gene and the same genetic manipulation practice. And each GM strain should be clearly named or coded.
1.3 Experiment site location and scale: **no more than three provinces and**	1.3 Experiment site location and scale: **experiments should be**

no more than 3 sites for each province. The total scale of animals for experiment (maximum) is 20 big animals (horses, cattle), 40 medium and small animals (pigs and sheep etc.), 200 of poultry (chickens and ducks etc.) and 200 fish. The province (municipality, autonomous region), county (city), town and village of the location of the experiment site should be clearly identified.	**conducted in the experiment base of the legal entity. The scale of animals for experiment in each experiment site (maximum)** is 20 big animals (horses, cattle) 40 medium and small animals (pigs and sheep etc.), 200 poultry (chickens and ducks etc.) and 200 fish. The province (municipality, autonomous region), county (city), town, village and **coordinates** of the location of the experiment site should be clearly identified.
	1.5.4 The operational procedure for the pilot experiment (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms for animal use, the handling of accidental release and the management of the experiment sites etc..
2.2 Number of strains of GM microorganisms used in experiment: **no more than 5 strains** for one application. These strains should be obtained using the same strain of recipient microorganism, the same target gene and the same genetic manipulation practice. Each strain should be clearly named or coded and be consistent with the name or code used in the pilot experiment stage.	2.2 Number of strains of GM microorganisms used in experiment: strains in one application should be obtained using the same strain of recipient microorganism, the same target gene and the same genetic manipulation practice. Each strain should be clearly named or coded and be consistent with the name or code used in the pilot experiment stage.
2.3 Experiment site location and scale: **no more than three provinces (municipalities, autonomous regions) and no more than three sites for each province. The total scale of animals for experiment (maximum)** should be 100 big animals (horses, cattle), 500 medium and small animals (pigs and sheep etc.), 5000 poultry (chickens and ducks etc.) and 10000 fish. The province (municipality, autonomous region), county (city), town and village of each experiment site should be clearly identified.	2.3 Experiment site location and scale: **the scale of animals for experiment in each experiment site (maximum)** should be 100 big animals (horses, cattle), 500 medium and small animals (pigs and sheep etc.), 5000 poultry (chickens and ducks etc.) and 10000 fish. The province (municipality, autonomous region), county (city), town, village and **coordinates** of each experiment site should be clearly identified.
	2.5.6 The operational procedure for the environmental release (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms for animal use, the handling of accidental release and the management of the experiment sites etc.)
3.2 Number of strains of GM microorganisms for experiment: only **one**	3.2 Number of strains of GM microorganisms for experiment:

strain of GM microorganism for animal use in one application. Its name should match the name and code in the previous experiment stages.	no more than **five strains of** GM microorganisms for animal use in one application. **The strains should be obtained from the same recipient strain, the same target gene and the same genetic manipulation practice.** The name of each strain should match the name or code in the previous experiment stages.
3.3 Experiment site location and scale: experiments should be conducted in provinces (municipalities, autonomous regions) where environment release has been approved of. **But there should be no more than two provinces (municipalities, autonomous regions) and no more than three sites for each province. The total scale of animals for experiment (maximum)**is 1000 big animals (horses, cattle), 10000 medium and small animals (pigs, sheep), 20,000 poultry (chickens, ducks etc.) and 100,000 fish etc. The province (municipality, autonomous region), county(city), town and village of the location of each experiment site should be clearly identified.	3.3 Experiment site location and scale: experiments should be conducted in provinces (municipalities, autonomous regions) where environment release has been approved of. **The scale of animals for experiment in each experiment site (maximum)** is 1000 big animals (horses, cattle), 10000 medium and small animals (pigs, sheep), 20,000 poultry (chickens, ducks etc.) and 100,000 fish etc. The province (municipality, autonomous region), county (city), town, village and **coordinates** of the location of each experiment site should be clearly identified.
	3.5.8 The operational procedure for the productive field trial (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms, the handling of accidental release and the management of the experiment sites etc.)
4.1 Title of project: should include the name of the target gene, of the GM microorganism and of t**he applicable province (municipality, autonomous region) of the safety certificate**, for example, the safety certificate for the recombinant fowlpox virus genetic engineered vaccine NF 16 expressing Newcastle disease virus F gene **in Shandong**.	4.1 Title of project: should include the name of the target gene and of the GM microorganism, for example, the safety certificate for the recombinant fowlpox virus genetic engineered vaccine NF16 expressing Newcastle disease virus F gene.
4.3 Only one safety certificate can be applied for a GM microorganism for animal use in one provincial level administrative region where the productive field trial has been approved of.	**deleted**
4.6 GM microorganisms for animal use should be granted for productive field trial by the Ministry of Agriculture and pass the trial prior to the application for a safety certificate.	**deleted**
Appendix III: III. Other safety assessment of GM microorganisms	**Appendix III: III. Other safety assessment of GM**

(III)Requirements for the application of other GM microorganisms at different stages	microorganisms (III)Requirements for the application of other GM microorganisms at different stages
1.2 Number of the strains of GM microorganisms for experiment: **should not exceed 20** in one application. The strains should be obtained from the same species of recipient microorganisms (no more than five strains of recipients)，the same target gene and the same genetic manipulation practice. And each GM strain should be clearly named or coded.	1.2 Number of the strains of GM microorganisms for experiment: the strains in an application should be obtained from the same species of recipient microorganisms (no more than five strains of recipients)，the same target gene and the same genetic manipulation practice. And each GM strain should be clearly named or coded.
1.3 Experiment site location and scale: **no more than two provinces (municipalities, autonomous regions) and no more than three sites for each province. The total scale should not exceed** 100 liters (kilograms) of fermented products (samples) or four mus of land area. The province (municipality, autonomous region), county (city), town and village of the location of each experiment site should be clearly identified.	1.3 Experiment site location and scale: **experiments should be conducted in the experiment base of the legal entity. The scale of each experiment site** should not exceed 100 liters (kilograms) of fermented products (samples) or four mus of land area. The province (municipality, autonomous region), county (city), town, village and **coordinates** of the location of each experiment site should be clearly identified.
	3.5.8 The operational procedure for the pilot experiment (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms, the handling of accidental release and the management of the experiment sites etc.)
2.2 Number of GM microorganism materials for experiment in an application: **should not exceed five**. The strains should be obtained from the same recipient microorganism, the same target gene and the same genetic manipulation practice. The name or code of each strain should be consistent with that in the pilot experiment.	2.2 Number of GM microorganism materials for experiment in an application: the strains should be obtained from the same recipient microorganism, the same target gene and the same genetic manipulation practice. The name or code of each strain should be consistent with that in the pilot experiment.
2.3 Experiment site location and scale: **no more than two provinces (municipalities, autonomous regions) and no more than five sites for each province. The total scale should be 100 to 1000 liters (kilograms) of fermented products (samples) or four to thirty mus of land area**. The province (municipality, autonomous region), county (city), town and village of the location of each experiment site should be clearly identified.	2.3 Experiment site location and scale: **the sale of each experiment site should not exceed 1000 liters (kilograms)[generally more than 100 liters(kilograms)] fermented products (samples) or no more than 30 mus/ (generally above 4 mus/0.27 ha)of land area.** The province (municipality, autonomous region), county (city), town, village and **coordinates** of the location of each experiment site should

	be clearly identified.
	2.5.6 The operational procedure for the environmental release (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms, the handling of accidental release and the management of the experiment sites etc.)
3.2 Number of GM microorganism materials for experiment in one application: **can only cover one** GM microorganism strain (line) and its name should be consistent with the name or code in preceding experiments.	3.2 Number of GM microorganism materials for experiment in one application: **no more than five** GM microorganism strains (lines).**The strains (lines) should be obtained from the same recipient strain, the same gene and the same genetic manipulation practice,** and its name should be consistent with the name or code in preceding experiments.
3.3 Experiment site location and scale: experiments should be conducted in provinces (municipalities, autonomous regions) where environmental release has been approved. **No more than two provinces (municipalities, autonomous regions) should be selected and no more than three sites should be selected in each province. The total scale** should be more than 1000 liters (kilograms) of fermented products (samples) or more than 30 mus (2 ha) of land area. The province (municipality, autonomous region), county (city), town and village of the location of each experiment site should be clearly identified.	3.3 Experiment site location and scale: experiments should be conducted in provinces (municipalities, autonomous regions) where environmental release has been approved of. Th**e scale of each experiment site** should be more than 1000 liters (kilograms) of fermented products (samples) or more than 30 mus(2 ha) of land area. The province (municipality, autonomous region), county (city), town, village and **coordinates** of the location of each experiment site should be clearly identified.
	3.5.8 The operational procedure for the productive field trial (including measures taken for the storage, transfer, disposal and post-experiment monitoring of GM microorganisms, the handling of accidental release and the management of the experiment sites etc.)
4.1 Project title: should include the name of the target gene, of the microorganism and of **the province (municipality, autonomous region) where the safety certificate can be applied** etc., for example, the safety certificate of ×××gene transferred ×××(name of the microorganism) **in ××× Province (municipality, autonomous region)**.	4.1 Project title: should include the name of the target gene and of the microorganism, for example, the safety certificate of ×××gene transferred ×××(name of the microorganism).
4.3 A safety certificate should be applied for one GM microorganism strain (line) in a provincial level administrative region where the	**deleted**

productive field trial has been approved.	